JUN 13 2011

Medacta International

510(k) Summary

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Contact Person: Mr. Adam Gross
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Date Prepared: March 28, 2011

DEVICE INFORMATION

Trade/Proprietary Name: MectaLIF
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar

21 CFR 888.3080
Class II
Device Product Codes: MAX

Predicate Devices: P960025 Lumbar I/F Cage
K072791 Opal Spacer
K081917 Devex and Leopard Systems
K073291 Capstone Spinal System
K040536 Verte-Stack Boomerang
K100175 Clydesdale Spinal System

Product Description:
The MectaLIF family is characterized by different sizes of PEEK (Polyetheretherketone) implants that can be applied with common surgical techniques such as PLIF (Posterior Lumbar Intervertebral Fusion) and TLIF (Transforaminal Lumbar Intervertebral Fusion). The MectaLIF family consists of the PEEK Oblique Interbody Fusion Device (33 sizes) and PEEK Posterior Interbody Fusion Device (28 sizes).
The PEEK Oblique and Posterior Interbody Fusion Devices are used to replace a degenerative disc in order to restore the height of the spinal column structure. They are made of PEEK and contain Tantalum Markers. The devices are intended to be used in combination with posterior fixation (e.g. Pedicle Screw System) as well as an autogenous bone graft.

Indications for Use:
The MectaLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Comparison to Predicate Devices
The MectaLIF family is similar to the Depuy Acromed Lumbar I/F Cage, Synthes Opal Spacer (OPAL), Depuy Devex and Leopard Systems, and the Medtronic Capstone Spinal System (Capstone). All of these devices are intervertebral fusion devices with bone graft for the lumbar spine. They are all used for the same clinical condition or purpose, which is degenerative disc disease between L2 (2nd Lumbar Vertebrae) and S1 (1st Sacral Vertebrae). They are all indicated for use in combination with supplemental fixation as well as in combination with autogenous bone graft. The Lumbar I/F Cage, OPAL, and Capstone have a similar surgical procedure to the MectaLIF Posterior as all utilize the PLIF Posterior Lumbar Interbody Fusion (Posterior Approach). The OPAL, Capstone, Devex, and Leopard Systems have a similar surgical procedure to the MectaLIF Oblique as all utilize the TLIF Transforaminal Lumbar Interbody Fusion (Unilateral Approach). The MectaLIF Posterior and MectalIF Oblique have similar geometrical features to the Lumbar I/F Cage, OPAL, and Capstone. The Lumbar I/F Cage and Devex System are similar to MectaLIF Posterior and Oblique implants in that all are offered with and without lordosis. The MectaLIF family uses similar materials in contact with the same tissue or body fluids as the OPAL, Capstone, and Verte-Stack Boomerang (Boomerang). The MectaLIF implants consist of Implant Grade Polyetheretherketone PEEK (ASTM F 2026), which is also used in the OPAL, Capstone, and Boomerang. The Tantalum (ISO 13782 / ASTM F 560) markers are also used in the Lumbar I/F Cage and the Boomerang system. The MectaLIF biomechanical features are similar to the OPAL, Devex, and Boomerang. The MectaLIF Posterior and Oblique implants have similar static compression strength to the Lumbar I/F Cage and Boomerang, similar dynamic compression strength to the OPAL and Boomerang,

similar dynamic compression/shear strength to the OPAL, and similar subsidence resistance to the Devex. The MectaLIF Oblique has a similar size range as the Medtronic Clydesdale Spinal System which has a maximum length of 40mm.

Performance Testing
Similar static compression strength - ASTM F 2077
Similar dynamic compression strength - ASTM F 2077
Similar dynamic compression/shear strength - ASTM F 2077
Similar subsidence resistance - ASTM F 2267

Conclusion:
Based on the above information, the MectaLIF implants can be considered as substantially equivalent to their predicate devices regarding clinical, technical, material and biomechanical aspects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K110927
Trade/Device Name: MectaLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 28, 2011
Received: April 01, 2011

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110927

Device Name: MectaLIF

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Prescription Use ___x___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110927